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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,319	10/26/2001	Michael R.S. Hill	P-10124.00	3335

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EXAMINER	
OROPEZA, FRANCES P	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,319	HILL ET AL.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/29/05 (Amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/ Restriction

1. In the response of 6/29/05, the Applicant amended the claims hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 102

2. Claims 20, 22-24, 26-28 and 31-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Holmstrom et al. (EP 0 688 577 A1). Holmstrom et al. disclose a device for impending supraventricular heart therapy comprising an implantable cardiac and neural electrode system to sense and stimulate (23), a detection block (5) of cardiac (51) and neural (53) sensing circuits to sense the physiological parameter(s), a neural stimulation circuit (9), a control circuit (13), and a pacing circuit (7) (figure 1). The therapy is provided for impending ventricular tachyarrhythmias, hence the system anticipates the occurrence of a cardiac insult. The neural generator includes a time control unit (92) that is programmed, hence the device is capable or teaches neural stimulation prior to onset of the insult, for a period to time after the onset of the insult, or for a time period after termination of the insult. The stimulator can be used externally with external and internal electrodes, read as positioned proximate an external body surface and positioned subcutaneously, respectively (abstract; figure 1; col. 3 @ 6-27 and 37-50; col. 4 @ 1-50; col. 5 @ 10-39; col. 7 @ 43-52; col. 8 @ 10-56; col. 9 @ 10-13 and 40-44).

As to claims 20, 31 and 32 and the use of the device with the excitable neural tissue of a portion of the spine, Holmstrom et al. discloses the use of the device with excitable neural tissue of a portion of the spine, specifically the ganglion stellatum (col. 3 @ 6-27; col. 7 @ 50). Note that the concept of using of the device with the excitable neural tissue of a portion of the spine amounts to an intended use limitation of which the device performs or is capable of performing.

As to claims 20, 31 and 32 and closed loop control of the stimulation system, Holmstrom et al. discloses closed loop control of the stimulation system (col. 4 @ 29-50; col. 5 @ 10-39; col. 6 @ 54 – col. 7 @ 7; col. 7 @ 53 – col. 8 @ 56).

3. Claims 20, 22-24, 26 and 29-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartlaub (US 6134470). Hartlaub discloses a method and device with physiological sensors (342), sensor controls (340), neural stimulator (272) and controllers (270, 244) to detect the precursors to tachyarrhythmias and respond with stimulation of the spinal cord/ spinal roots, pacing therapy and/or a drug delivery system. The therapy is provided for the precursors to tachyarrhythmias, hence the system anticipates the occurrence of a cardiac insult. The spinal cord generator is activated for predetermined time periods, hence the device is capable or teaches neural stimulation prior to onset of the insult, for a period to time after the onset of the insult, or for a time period after termination of the insult. The results of past stimulation are used to perform future stimulation (abstract; figures 1, 2; col. 1 @ 42-52; col. 2 @ 3-15 and 40-53; col. 4 @ 35-47; col. 4 @ 56 – col. 5 @ 7; col. 6 @ 25-54col. 7 @ 47-61; col. 8 @ 66 – col. 9 @ 20; col.9 @ 53-67; col. 11 @ 24-65; col. 12 @ 19-25;

col. 13 @ 4-34).

As to claims 20, 31 and 32 and the use of the device with the excitable neural tissue of a portion of the spine, Hartlaub discloses the use of the device with the excitable neural tissue of a portion of the spine, the spinal cord (col. 1 @ 5-9; col. 4 @ 35-47). Note that the concept of using of the device with the excitable neural tissue of a portion of the spine amounts to an intended use limitation of which the device performs or is capable of performing.

As to claims 20, 31 and 32 and closed loop control of the stimulation system, Hartlaub discloses closed loop control of the stimulation system (abstract; col. 1 @ 45-52; col. 6 @ 44-54; col. 9 @ 15-19)

4. Claims 20-22, 26, 31, 32 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Obel et al. (US 5199428). Obel et al. disclose a nerve stimulator (108) and pacing therapy (104) to respond to a physiological parameter (pH and SO2) which provides "a meaningful predictor of ischemia" and potential arrhythmias to the controller (100). The therapy is provided for "a meaningful predictor of ischemia" and potential arrhythmias, hence the system anticipates the occurrence of a cardiac insult. A patient activation mechanism is taught (abstract; figure 2; col. 5 @ 25-51; col. 6 @ 39-53; col. 7 @ 5-25; col. 10 @ 3-5).

As to claims 20, 31 and 32 and the use of the device with the excitable neural tissue of a portion of the spine, Obel et al. discloses the use of the device with the excitable neural tissue of a portion of the spine, the "other effective nerves" read as the ganglion stellatum associated with the Autonomic Nervous System (col. 1 @ 9-13;

col. 3 @ 8-19). Note that the concept of using of the device with the excitable neural tissue of a portion of the spine amounts to an intended use limitation of which the device performs or is capable of performing.

As to claims 20, 31 and 32 and a closed loop control of the stimulation system, Obel et al. discloses a closed loop control of the stimulation system (abstract; col. 5 @ 25-51; col. 6 @ 39-53; col. 7 @ 5-25).

5. Claims 20, 22-26, 31, 32 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Sweeney et al. (US 6272377). Sweeney et al. disclose a cardiac management system that predicts arrhythmias, based on physiological parameter(s), and treats the anticipated occurrence of a cardiac insult with neural stimulation. A warning is provided to the patient that an arrhythmia has been predicted (abstract; col. 1 @ 7-11; col. 2 @ 11-16, 39-45 and 58-66; col. 4 @ 61 – col. 5 @ 20; col. 8 @ 23-55; col. 9 @ 3-32 and 45-62).

As to claims 20, 31 and 32 and the use of the device with the excitable neural tissue of a portion of the spine, Sweeney et al. discloses the use of the device with the excitable neural tissue of a portion of the spine, specifically the stellate ganglion (col. 8 @ 49-53). Note that the concept of using of the device with the excitable neural tissue of a portion of the spine amounts to an intended use limitation of which the device performs or is capable of performing.

As to claims 20, 31 and 32 and closed loop control of the stimulation system, Sweeney et al. discloses closed loop control of the stimulation system (abstract; col. 4 @ 61 – col. 5 @ 20).

Statutory Basis

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

FPO 8/31/05

Frances P. Oropeza
Patent Examiner
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Robert E. Pezzuto
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